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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,519	09/18/2000	Michael C. Barney	660005.98757	4670
26710	7590	06/08/2004	EXAMINER	
QUARLES & BRADY LLP 411 E. WISCONSIN AVENUE SUITE 2040 MILWAUKEE, WI 53202-4497			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/664,519

**Applicant(s)**

BARNEY ET AL.

**Examiner**

Chih-Min Kam

**Art Unit**

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-8,12,14,15,17-23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 12, 14, 15, 17-23 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1, 3-8, 12, 14, 15, 17-23 and 25 are pending.

Applicants' amendment filed April 6, 2004 are acknowledged, and Applicants' response has been fully considered. Claims 1, 12, 15 and 23 have been amended. Thus, claims 1, 3-8, 12, 14, 15, 17-23 and 25 are examined.

### **Objection Withdrawn**

2. The previous objection of claims 8 and 22, is withdrawn in view of applicant's amendment to the claim in the amendment filed April 6, 2004.

### **Rejection Withdrawn**

#### ***Claim Rejections - 35 USC § 103(a)***

3. The previous rejection of claims 1, 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Nutter *et al.* (WO 98/11883) in view of Todd *et al.* (U. S. Patent 5,082,975), is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 7-9 in the amendment filed April 6, 2004.

4. The previous rejection of claims 3-5, 12, 14, 15, 17-21, 23 and 25 under 35 U.S.C. 103(a) as being unpatentable over Nutter *et al.* (WO 98/11883) in view of Todd *et al.* (U. S. Patent 5,082,975) as applied to claims 1, 6 and 7, further in view of Lefren *et al.* (U. S. Patent 4,431,427), is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 7-9 in the amendment filed April 6, 2004.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 3-8, 12, 14, 15, 17-23 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3-8, 12, 14, 15, 17-23 and 25 are directed to a method for affecting the growth of *Staphylococcus aureus* in an environment containing *S. aureus* or in the vaginal area with a compound of hexahydro beta acids, hexahydro beta salts, tetrahydroiso alpha acids or tetrahydroiso alpha salts, in an amount effective to kill, inhibit or control the growth of *S. aureus* without preventing the growth of *lactobacillus* at a pH of 4.5-5.0, wherein the concentration of the compound is about 0.2 to 25 ppm (claims 1, 3-8, 15 and 17-22); and a product comprising an absorbent material and a compound of hexahydro beta acids, hexahydro beta salts, tetrahydroiso alpha acids or tetrahydroiso alpha salts, in an amount effective to kill, inhibit or control the growth of *S. aureus* without preventing the growth of *lactobacillus* at a pH of 4.5-5.0, wherein the concentration of the compound is about 0.2 to 25 ppm (claims 12, 14, 23, and 25). The specification indicates the hop acids tetrahydroiso alpha and hexahydro beta have different bacteriocidal or bacteriostatic effects against *lactobacillus* as compared to *S. aureus* with *S. aureus* being more sensitive than *lactobacillus* (page 4, lines 28-35). The specification further asserts that *lactobacillus* exhibited strong growth in concentrations of hexahydro beta acids and tetrahydroiso alpha acids as high as 12.5 ppm, in contrast, *S. aureus* showed no to weak growth

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in the concentrations of the two hop acids as low as 1.56 ppm; and the sensitivity of *S. aureus* appeared to increase under acidic conditions, with the minimum inhibitory concentration (MIC) decreasing to 0.78 ppm at pH 6.0 and to less than 0.2 ppm at pH 5.0, and normally the pH of the vagina is about pH 4.5 to 5.0 (page 7, lines 8-18; Tables 1 and 2). However, the specification has not described the minimum inhibitory concentration of the two hop acids against *lactobacillus* at pH 4.5 to 5.0 (only at pH 6.3 in Table 2), nor has demonstrated the growth of *lactobacillus* at the concentration of 0.2 to 25 ppm of hexahydro beta acids and tetrahydroiso alpha acids at pH 4.5 to 5.0. Furthermore, the specification has not indicated a product comprising an absorbent material and a compound of hexahydro beta acids, hexahydro beta salts, tetrahydroiso alpha acids or tetrahydroiso alpha salts, in an amount effective to kill, inhibit or control the growth of *S. aureus* without preventing the growth of *lactobacillus* at a pH of 4.5-5.0, and at the concentration of 0.2 to 25 ppm of the compound. Although the data (Tables 1 and 2) indicate *S. aureus* is more sensitive toward the hop acids than *lactobacillus* at pH about 6, without further experimentation it would be impossible to predict the effects of a lower concentration of hexahydrocolupulone (such as in the range of 0.2-25 ppm) on the growth of *lactobacilli* as indicated in applicant's response (page 8, last paragraph). The lack of description of the effect of low concentrations (0.2-25 ppm) of the hop acids on the growth of *lactobacilli* at pH 4.5 to 5.0 as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

### ***Conclusion***

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9. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 160

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Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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June 2, 2004